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10/735,118	12/11/2003	Sarah S. Bacus	CST-213	4570

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,118	BACUS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *84-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *84-110* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Response filed May 30, 2007 to the restriction requirement of October 4, 2006 is acknowledged and has been entered. Claims 84-110 are currently being examined.

2. Upon review and reconsideration and in view of the Interview between Andrew Warner, James Cullem, Shanon Foley and Yvonne Eyler on May 11, 2007, the previous restriction requirement is hereby vacated.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1, Claims 84-107 drawn to a method for identifying a Her-2 overexpressing mammalian tumor that is likely to respond to a Her-2 directed therapy, classified in Class 435, subclasses 4 and 7.1.

Group 2, Claims 108-110 drawn to a kit comprising two or more antibodies classified in Class 530, subclass 387.1.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 2 and 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* э **806.05(h)**]. In the instant case the kit antibodies as claimed can be used in a materially different process such as production of anti-idiotypic antibodies.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given

above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must **include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which

of these claims are readable on the elected invention. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Group 1 is directed to the following patentably distinct species wherein the species are all drawn to a method for identifying a Her-2 overexpressing mammalian tumor that is likely to respond to a Her-2 directed therapy as follows:

(a) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody;

(b) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as

$2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody;

(c) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody.

(d) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody;

(e) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as

$2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody;

(f) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody.

(g) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a nucleic acid probe;

(h) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of

polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a nucleic acid probe;

(i) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a nucleic acid probe.

(j) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a nucleic acid probe;

(k) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of

polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a nucleic acid probe;

(l) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a nucleic acid probe.

(m) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a polypeptide probe;

(n) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated

AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a polypeptide probe;

(o) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is a polypeptide probe.

(p) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a polypeptide probe;

(q) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated

AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a polypeptide probe;

(r) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is a polypeptide probe.

(s) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody, nucleic acid probe and peptide probe;

(t) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more

polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody, nucleic acid probe and peptide probe;

(u) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is likely to respond to HER-2 directed therapy, wherein the probe is an antibody, nucleic acid probe and peptide probe;

(v) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody, nucleic acid probe and peptide probe;

(w) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody, nucleic acid probe and peptide probe;

(x) the method comprising the step of assaying a sample obtained from the mammalian tumor to detect a pattern of expression and phosphorylation of two or more polypeptides wherein the polypeptides are IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of polypeptides are claimed, wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$, wherein patient is not likely to respond to HER-2 directed therapy as claimed and contemplated in the specification, wherein the probe is an antibody, nucleic acid probe and peptide probe.

For a total of 1397 species.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species, that is each set of polypeptides comprises a different set of polypeptides, different one from the other, wherein each set of polypeptides is drawn to assay of a different parameter, that is expression alone, phosphorylation alone or both phosphorylation so that the assays are different one from the other, wherein in probes used in the assay are

different one from the other, that is the probes are nucleic acid probes alone which have a different structure and function from antibody probes alone are both different from peptide probes alone, wherein the probes are all of antibody, nucleic acid probes and peptide probes which together have different structures and functions form the probes used alone, wherein the outcomes are different one from the other wherein the assay indicates that the tumor is likely to respond to therapy or not likely to respond to therapy. In addition, these species are not obvious variants of each other based on the current record.

7. Group 2 is directed to the following patentably distinct species wherein the species are all drawn to a kits comprising antibodies with different structures and functions wherein the kits comprise anti-Her-2 antibody and one or more of antibodies against IGFR polypeptide, phosphorylated S6 ribosomal polypeptide, NDF polypeptide, EGFR polypeptide, phosphorylated AKT polypeptide, phosphorylated ERK polypeptide, wherein 57 combinations of antibodies in kits claimed have been determined wherein the number of combinations was calculated as $2^N - (N+1) = 2^6 - (6+1) = 64-7 = 57$.

For a total of 57 species.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species, that is each set of antibodies comprises a different set of antibodies, different one from the other, wherein each antibody has a different structure and function in that it binds to a different polypeptide. In addition, these species are not obvious variants of each other based on the current record.

It is further noted that the species claimed in Groups 1 and 2 are related as combination and subcombination. Inventions in this relationship are distinct if it

can be shown that (1) the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the patentability of the combination does not rely necessarily and solely on the patentability of any one subcombination as clearly evidenced by the plural subcombinations claimed. Further, each of the subcombinations has utility by itself because each of the subcombinations are useful for screening for different variables and different markers. Thus the claims are distinct as required by MPEP 806.05(c).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must **include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under *35* U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the

time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not

be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar, PhD
Primary Patent Examiner
August 14, 2007